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REMARKS/ARGUMENTS

The Examiner withdrew claims 20 to 23 and 38 to 46 from further consideration pursuant to 37 CFR 1.42(b) as being drawn to a non-elected invention. These claims have been deleted from the application without prejudice to the applicants right to file a divisional or continuation application directed thereto.

The allowance of claims 1 to 19 is gratefully acknowledged.

The Examiner rejected claims 24, 30, 31 and 37 under 35 USC 102(b) as being anticipated by Servidio (US Patent No. 5,927,274). Reconsideration is requested having regard to the following remarks.

Comparing the device for detecting onset of inspiratory effort (T_{onset}) in a patient on mechanical ventilation claimed in claim 24 with the device described in Servidio, there are important distinctions which distinguish claim 24 from the cited prior art, as discussed below.

Both devices include sensors to measure pressure (item 4 in Figure 7 of this application, item 280 in Figure 11B of Servidio) and flow (item 5 in Figure 7 of this application, item 252 in Figure 11B of Servidio). As is usual with outputs of such sensors, it is necessary to process these outputs using amplifiers and signal conditioners that are appropriate for the sensor used in order to provide pressure and flow signals in conventional units (e.g. cmH_2O in the case of pressure and L/sec. in the case of flow). These amplifiers/conditioning elements are shown in Figure 7 of the present invention as Low pass filter and offset and gain circuitry connected to each sensor, gain circuitry being another term for amplifier. The corresponding elements in Servidio are amplifier 282 in Figure 11B for generating a pressure signal and amplifier 266 in Figure 11B to generate a flow signal. The outputs of the amplifiers (282 and 266) represent simple pressure (in cmH_2O) and flow (in L/second) signals corresponding to signals 15 and 9, respectively in the present invention (see Figures 7 and 8). Both devices also share elements to

integrate flow in order to provide a signal corresponding to volume inspired and expired by the patient. In the device of the present invention, this is given by the integrator (item 79, Figure 8) and in Servidio by the tidal volume circuitry (item 288, (Figure 11B).

The generation of signals corresponding to pressure, flow and volume is almost universal in ventilation devices and does not represent themselves inventive steps, but rather the signals are simply necessary inputs to accomplish the inventive steps effected by the device. The inventive steps in Servidio relate to a special mechanical valve design to regulate the pressure and to the location of said valve to minimize noise and contamination. The pressure signal in Servidio is used to effect appropriate control of the valve whereas the flow and volume signals are used to estimate leaks in order to estimate patient flow for the sake of triggering and display of patient ventilation. On the other hand, the device of the invention uses the pressure, flow and volume signals to generate a novel signal corresponding to the pressure generated by the patient's own respiratory muscles which is then used to trigger the inspiratory and expiratory phases of the ventilator.

The device claimed in claim 24 requires certain elements, as defined in the claim, to produce the above-noted result. Thus:

a) Further processing of the flow signal (9) is effected to convert it into pressure. This is achieved by a second gain control (19) referred to as Kf (Figure 8), that is adjustable from patient to patient by the Kf adjust input (Figure 8) to accommodate differences in patient resistance and to make it possible to adjust the baseline of the composite signal (item 31, Figure 8). Servidio does not incorporate such second gain control of the flow signal to convert it into pressure and there is no external input that permits changes in the gain of the only flow amplifier used (item 266, Figure 11B). Rather the flow signal is used as a flow signal in all subsequent applications, in Servidio.

b) Further processing of the volume signal (item 79, Figure 8) is effected to convert volume into pressure. This is achieved by a separate gain control (24) referred to as Kv (Figure 8), that is adjustable from patient to patient by the Kv adjust input (Figure 8) to accommodate differences in patient elastance and to make it possible to adjust the baseline of the composite signal (item 31, Figure 8). Servidio does not incorporate such gain control of the volume signal to convert it into pressure and there is no external input that permits changes in the value of such a gain control since none exists.

c) Thus, applicants device employs two amplifier devices as claimed in lines 5 to 8 of claim 24, so that there are three signals, namely the airway pressure signal, the gas flow pressure signal and the gas volume signal. These three signals are summed by a summing amplifier (item 16, Figure 8) to provide a signal that reflects the pressure output of patient's muscles. There is nowhere in Servidio that refers even remotely to summing pressure, flow and volume signals, with or without prior conversion of the flow and volume signals into pressure. Figure 11A in Servidio shows all three signals (pressure, flow and volume) and being inputted into a microcontroller (item 225) but there is no indication in the specification that the microcontroller (item 225) sums these signals. Rather, it is clearly stated in column 15, line 64 that "... the microcontroller (225) controls the displays (226)". It is thus clear that the microcontroller (item 225) in Servidio receives the pressure, flow and volume inputs simply to channel them to the display module where they are displayed as such (i.e. pressure, flow and volume) (see Figure 2 of Servidio).

It is thus clear that the Servidio device neither contemplates, nor has the necessary components or steps to generate a composite signal that reflects patient effort. The summing amplifier is defined in lines 9 to 11 of claim 24.

d) In the device defined in claim 24, the composite signal is used to determine when inspiration begins and ends. By contrast, Servidio uses a most basic method of accomplishing this triggering function, namely monitoring the flow

signal (after subtracting leaks in this case; item 274, Figure 11B) and triggering inspiration when patient flow exceeds a threshold value and triggering expiration when patient flow declines below a threshold value. This result is achieved in Servidio by the Inspiration/Expiration Detect module (item 290, Figure 11B) the operation of which is described in detail in Figure 13. This figure and the associated text leave no doubt that triggering is effected by the flow signal and not by a composite signal as recited in claim 24. Thus, since Servidio does not generate a signal corresponding to the composite signal defined in claim 24 and does not utilize such a signal in the manner defined in claim 24, it follows that there is no overlap in the triggering functions of the two devices.

Although it is believed that the distinctions between claim 24 and the Servidio device are fully explained above, we wish to drawn attention to a possible source of confusion. Figure 9 in Servidio patent includes the terms Kf and Kv, which may be confused with similar terms used in applicants claims. This is an unfortunate coincidence since the terms refer to completely different functions. In claim 24, Kf refers to the resistance term that converts flow to pressure and signifies a constant (K) related to flow (f). In Servidio, Kf is a function within the actuator that regulates the force generated by the actuator and has nothing to do with patient flow. In addition, in claim 24, Kv refers to the elastance term that converts volume to pressure and signifies a constant (K) related to volume (v). In Servidio, Kv is a velocity transducer that measures the velocity of movement of the piston within the valve and has nothing to do with volume inhaled by the patient. We draw attention to these differences since the Examiner used the terms Kf and Kv in the Office Action in comparing Servidio to the subject matter claimed in claim 24.

Accordingly, it is submitted that Servidio does not anticipate claim 24. With respect to claims 30, 31 and 37, these claims are dependent on claim 24. In view of the demonstration above that claim 24 is not anticipated by Servidio, it is submitted that claims 30, 31 and 37 similarly are not anticipated by Servidio. It is

submitted, therefore, that the rejection of claims 24, 30, 31 and 37 under 35 USC 102(b) as being anticipated by Servidio et al, should be withdrawn.

The Examiner indicated that claims 25 to 29 and 32 to 36 were objected to as being dependent on a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. However, these claims are dependent, directly or indirectly, on claim 24 which has been demonstrated above to be patentable over the applied prior art. Accordingly, each of claims 25 to 29 and 32 to 36 is patentable over the applied prior art.

It is believed that this application is now in condition for allowance and early and favourable consideration and allowance are respectfully solicited.

Respectfully submitted,

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